UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,336	11/13/2003	Paul Ashton	CDSI-P01-030	9868

28120 7590 06/05/2009

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,336	ASHTON ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 12-37* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 12-17 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114 and the request for extension of time (3 months-granted), both filed 02/27/09 and the Amendment and Applicant's Arguments/Remarks, both filed 01/12/09 is acknowledged.

Claims 1 and 12-37 are pending in this action. Claims 1 and 31-33 have been amended. Claims 2-11 and 38 have been cancelled. Claims 18-20 remain withdrawn. Claims 1, 12-17 and 21-37 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 February 2009 has been entered.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 12-17 and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67 and 70-74 of copending Application No. 10/096,877 ('877 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '877 application also claims a sustained release drug delivery system comprising a drug reservoir comprising a therapeutically effective amount of an agent; an inner tube having first and second ends and covering at least a portion of said drug reservoir, said inner tube being dimensionally stable and capable of supporting its own weight; and an outer layer covering at least a portion of said drug reservoir and/or inner tube, wherein upon implantation, agent is released through at least one of the open ends.

The only differences observed between the '877 application and the instant claims are that claim 1 of '877 does not recite an impermeable member located at the inner tube, first end and does not recite a permeable member positioned at said inner tube first/second ends. However, note that claim 46 recites the limitation that the sustained release drug delivery system further comprises "an impermeable member positioned at said inner tube, first end". Also note claims 49 & 50, which recite the limitation that the sustained release drug delivery system further

comprises "a permeable member positioned at said inner tube first/second ends". Instant claim 1 recites a specific class of therapeutic agent – "antiviral", whereas claim 1 of '877 is generic and recites "an agent". However, note that claim 70 of '877 claims that the agent is an "anti-viral agent". Asides from these distinctions, the inventions of the instant application and the '877 application are essentially similar.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 12-17 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.* (U.S. Pat. No. 5,378,475) in view of Visser (U.S. Pat. No. 5,935,597).

Smith *et al.* ('475) teach sustained release drug delivery devices and methods for treating a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect. The device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. The first coating layer covers at least a portion of the inner core; however, at least a portion of the inner core is not coated with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core (see Abstract); (col. 1, lines 5-20).

Smith *et al.* teach that the first layer must be selected to be impermeable to the passage of the agent from the inner core out to adjacent portions of the second coating layer. The purpose is to block the passage of the agent to those portions and thus control the release of the agent out of the drug delivery device (col. 7, lines 10-33).

Natural or synthetic materials that can be used in the device include cross-linked polyvinyl alcohol, plasticized nylon, silicone rubbers and the like (col. 6, lines 41-66). See also column 8, lines 49-68).

Regarding Applicant's limitation of "an inner tube that is dimensionally stable and capable of supporting its own weight", it is the position of the Examiner that the coating(s) taught by Smith are sufficient to meet this limitation. Smith teach a coating layer that may be applied directly in the form of a *sheet or membrane* to the outer surface of the agent (col. 9, lines 1-34). This "sheet or membrane" can be interpreted as a solid layer that would be sufficient to support its own weight and would also be dimensionally stable. The inner tube claimed by Applicant has not been defined (*i.e.*, by reciting specific thickness parameters) so as to

distinguish over the coatings of Smith. The coatings of Smith could also be considered as rigid structures, capable of supporting their own weight.

Regarding the limitation that the 'outer layer covering only a portion of said inner tube', this limitation is met by Smith. Smith does not teach entire or complete coverage of the first layer and leaves a portion of the layer exposed.

Smith does not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teaches that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Smith. One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used for the beneficial treatment of viral infections and conditions. The expected result would be an enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

* * * * *

Claims 1, 12-17 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (U.S. Pat. No. 5,902,598) in view of Visser (U.S. Pat. No. 5,935,597).

Chen *et al.* ('598) teach a sustained release drug delivery device comprising an inner core or reservoir containing an active agent effective in obtaining a local or systemic physiological or pharmacological effect; a first coating which is permeable to the passage of the effective agent; a second coating containing an impermeable polymer and at least one impermeable disc essentially impermeable to the passage of the effective agent; and a third coating permeable to the passage of the effective agent. The first coating covers at least a portion of the inner core. The second coating covers at least a portion of the first coating layer and inner core; however, at least a small portion of the first coating layer or inner core is not coated with the second coating layer. The third coating layer essentially completely covers the first coating layer and the second coating layer. The portion of the first coating layer which is not coated with the second coating layer allows a passage of the agent into the third coating layer thus allowing controlled release (see col. 1, lines 5-23); (col. 3, lines 40-65).

The devices are particularly suitable for use in treating mammalian organisms infected with AIDS, as well as treating conditions, such as glaucoma, retinopathy, uveitis, keratitis and the like (col. 5, lines 60-68).

The devices can incorporate active agents, such as anti-viral agents, including idoxuridine (col. 6, lines 27-57).

Natural or synthetic materials that can be used in the device include cross-linked polyvinyl alcohol, plasticized nylon, silicone rubbers and the like (col. 7, lines 10-33).

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Regarding Applicant's limitation of "an inner tube that is dimensionally stable and capable of supporting its own weight", it is the position of the Examiner that the coating(s) taught by Chen are sufficient to meet this limitation. The inner tube claimed by Applicant has not been defined (*i.e.*, by reciting specific thickness parameters) so as to distinguish over the coatings of Chen. The coatings of Chen could also be considered as rigid structures, which upon drying and hardening of the coating layer would also be capable of supporting their own weight.

Chen does not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teaches that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Chen. One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used for the beneficial treatment of viral infections and conditions. The expected result would be an enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

* * * * *

Response to Arguments

Applicant's arguments filed 01/12/09 have been fully considered but were not found persuasive.

- **Double Patenting Rejection:**

Applicant argued, "Claims 1, 12-19, and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67 and 70-74 of copending application 10/096,877. Applicants will address this rejection when it is no longer provisional."

The double patenting rejection has been maintained. The instant claims have not been amended so as to overcome the double patenting rejection, nor has a terminal disclaimer been filed over the copending application 10/096,877. Please note that Applicants, in response to this Action, must specifically address the double patenting rejection by either traversing the rejection (by specifically pointing out the differences between the claims of the applications) or by stating on record that Applicants intend to file a terminal disclaimer to overcome the double patenting rejection. A request to hold a rejection in abeyance is not a proper response to a rejection. Rather, a request to hold a matter in abeyance may only be made in response to an OBJECTION or REQUIREMENTS AS TO FORM (see MPEP 37 CFR 1.111 (b) and 714.02). Applicants are kindly requested to respond accordingly, (either by traversing the rejection or by a statement of agreement/intention to file a terminal disclaimer), in order to avoid a notice of non-responsive amendment as the next Office Action.

- **35 U.S.C. 103(a) rejection of claims 1, 12-17 and 21-37 over Smith (US 5,378,475) in view of Visser (US 5,935,597):**

Applicant argued, "Applicants have amended the claims such that the sustained drug delivery system of the pending claims now includes an outer layer (corresponding to the second layer of Smith) which covers only a portion of the inner tube, whereas in Smith, the second layer essentially completely covers the first layer and the uncoated portion of the inner core."

Applicant's arguments have been fully considered but were not deemed persuasive. Smith does not teach entire or complete coverage of the first layer and leaves a portion of the layer exposed. Moreover, the limitation that the "outer layer covering only a portion of said

inner tube" is not defined to such a degree that would distinguish over the coated portion (first layer) disclosed by Smith. As noted above, Smith does not require that the first layer be completely or entirely covered by the second layer. As such, the device of Smith reads on the device as instantly presented.

Applicant argued, "The teachings of Visser (for drug nevirapine) are not sufficient to overcome the deficiencies of Smith".

This was not deemed persuasive. The secondary reference of Visser amply fills the deficiency of Smith, based on their teaching of suitable antiviral agents (i.e., nevirapine) for use in drug delivery devices. The reference of Visser establishes that it is well known to one of ordinary skill in this art to employ active agents such as antivirals (nevirapine), used for treatment of viral infections and conditions, delivered through delivery devices as claimed. Thus, ample motivation has been supplied based on the secondary references teaching of the use of antivirals in drug delivery devices.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

June 4, 2009